K081842

OCT - 3 2008

Premarket Notification 510(k) Summary
As required by section 807.92
Engstrom Ventilator

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc.
PO Box 7550
Madison, WI 53707 USA
Tel: 608-221-1551
Fax: 608-223-2496

NAME OF CONTACT:

Ms. Adrienne Lenz, RAC
Ms. Karla Krause (alternate)

DATE:

June 26, 2008

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Engström Carestation
Engström Pro

COMMON NAME:

Ventilator, Continuous

CLASSIFICATION NAME:

CBK, ventilator, continuous, facility use

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Engstrom Ventilator is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Engstrom Carestation (K062710) and the Maquet Servo-i (K063404, K041223).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The GE Datex-Ohmeda Engström family of ventilators (Engstrom Carestation and Engstrom Pro) are flexible, adaptable, and intuitive critical care ventilators. A wide selection of performance options gives the user full control of the system configuration. The Engström Carestation is a complete system featuring patient monitoring, patient ventilation, and the capability of interfacing with central information management systems. The Engstrom Pro is a defeatured variant of the Engström Carestation.

Both the GE Datex-Ohmeda Engstrom Carestation and Engstrom Pro are designed to provide mechanical ventilation for adults and pediatrics weighing 5kg and above having degrees of pulmonary impairment varying from minor to severe. Optional Neonatal capabilities on Engström Family expand its patient range to 0.5 kg.

The modes of ventilation are available include:

- Volume Controlled (VCV)
- Pressure Controlled (PCV)
- Pressure Controlled, Volume Guaranteed (PCV-VG)
- Synchronized Intermittent Mandatory Ventilation, Volume Controlled (SIMV-VC)
- Synchronized Intermittent Mandatory Ventilation, Pressure Controlled (SIMV-PC)
- Synchronized Intermittent Mandatory Ventilation, Pressure Controlled Volume Guarantee (SIMV-PCVG),
- Bi-level Airway Pressure Ventilation
- Constant Positive Airway Pressure/Pressure Support Ventilation (CPAP/PSV)
- Apnea backup (active in Bi-level and CPAP/PSV)
- Non-invasive ventilation (NIV), note that NIV is not available in neonatal mode
- Neonatal Nasal CPAP (nCPAP).

The GE Datex-Ohmeda Engström Carestation and Engström Pro are microprocessor based, electronically controlled, pneumatically driven ventilators that include integrated FiO2, airway pressure, spirometry and volume monitoring and an Aerogen Aeroneb nebulizer.

The ventilator consists of two main components: a display and a ventilator unit. The display allows the user to interface with the system and control settings. The ventilator unit controls electrical power, nebulization, and pneumatic gas flow to and from the patient. The Engstrom Carestation also includes a module bay that allows the integration of various Datex-Ohmeda patient monitoring modules with the ventilator.

The user interface for control of nebulization is provided via the ventilator display unit. The Aerogen Aeroneb Pro Nebulizer board (K021175) is provided standard with the unit. Nebulizers are options for both the Engström Carestation and Engström Pro.

The system is designed for facility use, including within-facility transport, and should only be used under the orders of a clinician.

Optional accessories common to both Engstrom Carestation and Engstrom Pro include a trolley/cart, integrated air compressor, support arm, humidifier and water trap mounting brackets, and auxiliary electrical outlets. The GE Datex-Ohmeda EV Air Compressor is intended for use as an accessory to provide a dry, filtered, breathable compressed air supply. The

compressor has no alarm functions. All alarm functions and reactions to failure of the compressed gas supply, are provided by the Engstrom Carestation or Engstrom Pro as cleared in K041775. The compressor is installed in the base of the ventilator cart. The compressor is powered from AC mains only. A source of compressed oxygen is required to be connected to Engstrom Carestation/Engstrom Pro equipped with the optional compressor.

Additional optional accessories specific to the Engstrom Carestation include airway modules, intratracheal pressue sensor, and module bay. Optional functionality specific to the Engstrom Carestation include neonatal use, integrated respiratory gas monitoring, capabilities to measure SpiroDynamics via a GE supplied intratracheal pressure sensor in patients using sized 6.5 tracheal tubes and larger, and calculation of functional residual capacity of mechanically ventilated patients using Nitrogen Wash In/Wash Out method. The integrated respiratory gas monitoring is provided via the Datex-Ohmeda M-Gas Module (M-C, M-CO, M-COV, M-COVX, M-CaiO, M-CAiOV, M-CAiOVX, (rev 3.2 software and higher) K# 001814) or Mini-CO2 Module (K023454) which are physically integrated into the Engstrom Carestation, receive electronic power from the Engstrom Carestation and communicate measured values to the Engstrom Carestation for display on the system display unit.

Enstrom Pro is a defeatured variant of the Engstrom Carestation. It uses the same hardware and software as the Engstrom Carestation, with the following differences:

- FRC and Spirodynamics are not available
- Monitoring module is not available
- Cart outlets are not available
- A new cart is provided
- Aesthetic differentiation

INTENDED USE as required by 807.92(a)(5)

The GE Datex-Ohmeda Engström family of ventilators (Engström Carestation and Engström Pro) are designed to provide mechanical ventilation for adults and pediatrics weighing 5kg and above having degrees of pulmonary impairment varying from minor to severe. Optional Neonatal capabilities on the Engström family expand the patient range to 0.5 kg.

The GE Datex-Ohmeda Engström family of ventilators are microprocessor based, electronically controlled, pneumatically driven ventilators that include integrated FiO2, airway pressure, spirometry and volume monitoring. Options include an Aerogen Aeroneb nebulizer and an integrated air compressor. Options available on Engström Carestation only include integrated respiratory gas monitoring capabilities via various Datex-Ohmeda patient monitoring modules listed in the product labeling, capabilities to measure SpiroDynamics via an intratracheal pressure sensor in patients using sized 6.5 tracheal tubes and larger, and calculation of functional residual capacity of mechanically ventilated patients using Nitrogen Wash In/Wash Out method.

Not all features are available with all patient populations.

The Engström Carestation is not a pulmonary function calculation device.

The system is designed for facility use, including within-facility transport, and should only be used under the orders of a clinician.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The GE Datex-Ohmeda Engstrom Carestation has been updated from the predicate version (K062710). There have been no changes to the intended use or fundamental scientific technology.

The software for the Engstrom Carestation has been updated to introduce several new features. The significant changes to the software include addition of ventilation modes for non-invasive ventilation and nasal CPAP in the neonatal mode of operation.

This submission also adds the Engstrom Pro ventilator, which is a defeatured variant of the Engstrom Carestation.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The GE Datex-Ohmeda Engstrom Carestation/Engstrom Pro have been thoroughly tested through verification of specifications and validation, including software validation. Verification of compliance with the following standards has also been made to support safe use of the device in its intended environment.

1. UL 2601 – General requirements for Medical Electrical Equipment
2. EN/IEC 60601-1: General requirements for Medical Electrical Equipment
3. EN/IEC 60601-1-2: 2001 - Medical Electrical Equipment - Electromagnetic Compatibility
4. EN 475 – Electrically Generated Alarm Signals
5. CGA V-1 ad ISO 5145 Medical Gas Cylinders – Threaded Cylinders
6. EN 980 Graphical Symbols
7. EN/IEC 60601-2-12, Medical Electrical Equipment – Critical Care Ventilators

SUMMARY OF CLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(2)

The modifications made to the Engstrom ventilator did not require clinical testing.

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Engstrom Carestation/Engstrom Pro ventilator as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2008

Ms. Adrienne Lenz
Regulatory Affairs Manager
Datex-Ohmeda, Incorporated
P.O. Box 7550
Madison, Wisconsin 53707

Re: K081842
Trade/Device Name: GE Datex-Ohmeda Engström Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: August 7, 2008
Received: August 13, 2008

Dear Ms. Lenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): K

Device Name: GE Datex-Ohmeda Engström Ventilator

Indications For Use:

The GE Datex-Ohmeda Engström family of ventilators (Engström Carestation and Engström Pro) are designed to provide mechanical ventilation for adults and pediatrics weighing 5kg and above having degrees of pulmonary impairment varying from minor to severe. Optional Neonatal capabilities on the Engström Family expand the patient range to 0.5 kg.

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Prescription Use _XXX_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081842